

United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/608,899	06/27/2003	Lisa M. Donnelly	022956-0218	7787	
21125 7590 05/04/2007 NUTTER MCCLENNEN & FISH LLP			EXAMINER		
	DE CENTER WEST		BLANCO, JAVIER G		
BOSTON, MA	BOULEVARD 02210-2604		ART UNIT	PAPER NUMBER	
			3738		
	,				
	•		MAIL DATE	DELIVERY MODE	
	•		05/04/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief

Application No.		Applicant(s)	
	10/608,899	DONNELLY ET AL.	
	Examiner	Art Unit	
	Javier G. Blanco	3738	·

	Javier G. Blanco	3738					
The MAILING DATE of this communication appe	ars on the cover sheet with the c	orrespondence add	ress				
THE REPLY FILED <u>23 April 2007</u> FAILS TO PLACE THIS APP	LICATION IN CONDITION FOR AL	LOWANCE.					
1. The reply was filed after a final rejection, but prior to or or this application, applicant must timely file one of the follow places the application in condition for allowance; (2) a Not a Request for Continued Examination (RCE) in compliant time periods:	wing replies: (1) an amendment, aft tice of Appeal (with appeal fee) in (fidavit, or other evider compliance with 37 C	nce, which FR 41.31; or (3)				
a) The period for reply expiresmonths from the mailin	g date of the final rejection.						
b) The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. I no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.							
TWO MONTHS OF THE FINAL REJECTION. See MPEP 7	Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).						
Extensions of time may be obtained under 37 CFR 1.136(a). The date have been filed is the date for purposes of determining the period of exunder 37 CFR 1.17(a) is calculated from: (1) the expiration date of the set forth in (b) above, if checked. Any reply received by the Office later may reduce any earned patent term adjustment. See 37 CFR 1.704(b)	tension and the corresponding amount shortened statutory period for reply orig r than three months after the mailing da	of the fee. The appropr inally set in the final Offi	iate extension fee ce action; or (2) as				
NOTICE OF APPEAL							
 The Notice of Appeal was filed on A brief in comp filing the Notice of Appeal (37 CFR 41.37(a)), or any exte a Notice of Appeal has been filed, any reply must be filed AMENDMENTS 	nsion thereof (37 CFR 41.37(e)), to	avoid dismissal of th	ns of the date of the appeal. Since				
3. The proposed amendment(s) filed after a final rejection,	but prior to the date of filing a brief	will not be entered b	ecance				
(a) They raise new issues that would require further co (b) They raise the issue of new matter (see NOTE below	nsideration and/or search (see NO		ccause				
(c) They are not deemed to place the application in be appeal; and/or	•	ducing or simplifying	the issues for				
(d) ☐ They present additional claims without canceling a NOTE: (See 37 CFR 1.116 and 41.33(a)).		ected claims.					
4. The amendments are not in compliance with 37 CFR 1.1		mpliant Amendment	(PTOL-324).				
5. Applicant's reply has overcome the following rejection(s)			, , .				
 Newly proposed or amended claim(s) would be a non-allowable claim(s). 	llowable if submitted in a separate,	•	_				
7. For purposes of appeal, the proposed amendment(s): a) how the new or amended claims would be rejected is pro The status of the claim(s) is (or will be) as follows:		II be entered and an e	explanation of				
Claim(s) allowed:	·						
Claim(s) objected to:							
Claim(s) rejected: <u>1-17, 20, and 21</u> . Claim(s) withdrawn from consideration:							
AFFIDAVIT OR OTHER EVIDENCE							
8. The affidavit or other evidence filed after a final action, but because applicant failed to provide a showing of good an was not earlier presented. See 37 CFR 1.116(e).							
9. The affidavit or other evidence filed after the date of filing entered because the affidavit or other evidence failed to showing a good and sufficient reasons why it is necessar	overcome <u>all</u> rejections under appe	al and/or appellant fa	ils to provide a				
10. ☐ The affidavit or other evidence is entered. An explanation REQUEST FOR RECONSIDERATION/OTHER	n of the status of the claims after e	entry is below or attacl	ned.				
11. The request for reconsideration has been considered bu	ut does NOT place the application i	n condition for allowa	nce because:				
12. ☐ Note the attached Information Disclosure Statement(s). 13. ☑ Other: See Continuation Sheet.	(PTO/SB/08) Paper No(s)						
	' <i>></i>						
CORRINE MCDERMOTT Javier G. Blanco							
SUPERVISORY PATENT EXAMINER April 27, 2007							

SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700

Continuation of 13. Other:

- 1. With regards to the 102(b) rejection based on Bolton (US 5,906,632 A), Applicants' arguments filed April 23, 2007 have been fully considered but they are not persuasive.
- Bolton clearly discloses the subject matter of a graft fixation device comprising:
- (i) A bioabsorbable (see column 4, lines 22-27) radially expandable sheath (anchor 20) having a bullet-shaped (see column 7, lines 1-4) slot-free distal tip (tip/point 222) with at least two sidewalls (212, 213) extending proximally therefrom and defining a central lumen (central lumen defined between bore 220 and bore 221), each sidewall having a substantially concave outer surface (grooves 210) capable of seating (see column 4, lines 8-15) a graft member (80, 82), and each sidewall being at least partially separated by a longitudinally oriented opening (groove 218) extending from a proximal end (223) along a substantial length of each sidewall and terminating at a position just proximal to the distal tip (i.e., it does NOT open/terminate in distal tip 222, therefore it does not create a slot/slit therein); and (ii) A bioabsorbable (see column 4, lines 42-44) sheath expander (screw 40) capable of being disposed in the central lumen of the radially expandable sheath, and CAPABLE OF flexing/deforming the concave outer surface of the sidewalls toward a circular geometry (see Figures 6A-6F; see column 4, lines 45-61). Alternatively, the "circular geometry" could be broadly interpreted as the circular geometry of the bone tunnel/bore (i.e., the concave outer surface of the sidewall will be deformed in the direction of the circular geometry of the bone tunnel/bore).
- 2. With regards to the 102(e) rejection as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Justin et al. (US 6,887,271 B2), Applicants' arguments filed April 23, 2007 have been fully considered but they are not persuasive. Justin et al. clearly disclose the subject matter of a graft fixation device comprising:
- (i) A bioabsorbable (see column 6, lines 34-38) radially expandable sheath (fixation members 20, 50) having a bullet-shaped slot-free distal tip (tip/point 112) with at least two sidewalls (see Figures 2 and 6) extending proximally therefrom and defining a central lumen (eyelet 24 and/or opening 22, 55), each sidewall having a substantially concave outer surface (grooves 23) capable of seating (see column 4, lines 15-20; column 5, lines 3-8; column 7, lines 48-54) a graft member (200), and each sidewall being at least partially separated by a longitudinally oriented opening (slots 24, 360, 370) extending from a proximal end along a substantial length of each sidewall and terminating at a position just proximal to the distal tip; and
- (ii) A bioabsorbable (see column 6, lines 34-38) sheath expander (expansion plug 21, 52, 310) capable of being disposed in the central lumen of the radially expandable sheath, and CAPABLE OF flexing/deforming the concave outer surface of the sidewalls toward a circular geometry (see column 4, lines 15-20; column 5, lines 3-8; column 7, lines 48-54). Alternatively, the "circular geometry" could be broadly interpreted as the circular geometry of the bone tunnel/bore (i.e., the concave outer surface of the sidewall will be deformed in the direction of the circular geometry of the bone tunnel/bore).
- 3. With regards to the 103(a) rejection based on Jacobs et al. (WO 02/32345 A2; cited in Applicants' IDS), Applicants' arguments filed April 23, 2007 have been fully considered but they are not persuasive.
- a. Regarding claim 1, the Applicants argue that Jacobs et al. does not disclose newly added (functional) limitation: "configured to deform the concave outer surface of the sidewalls toward a circular geometry". The Examiner respectfully disagrees. The "circular geometry" could be broadly interpreted as the circular geometry of the bone tunnel/bore (i.e., the concave outer surface of the sidewall is capable of being deformed/flexed in the direction of the circular geometry of the bone tunnel/bore). Also, the material of Jacobs et al.'s sheath/sleeve is the same as Applicants' sheath/sleeve, and intended for the same purpose (anchoring a ligament/tendon/graft). Expansion of the bioabsorbable radially expandable sheath (i.e., by introduction of an expander) will provide at the least some level of deformation of the concave surface towards a "circular geometry".
- b. Regarding claim 11, it will be inherent that a range of sheath & expander pairs will be available to the surgeon in the operating room so as to accommodate variations in drilled hole/tunnel sizes. The invention may comprise a kit of expandable sheaths and expanders, wherein a properly dimensioned (i.e., depends on the particular bone tunnel diameter and/or length) sheath/sleeve will receive a correspondingly dimensioned sheath/sleeve expander..